



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

91692d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

August 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 72

Anthony A. Palermo
Chief Executive Officer/Owner
Modern Products, Inc.
6425 W. Executive Drive
Mequon, Wisconsin 53092

Dear Mr. Palermo:

During our inspection on August 8-9, 2001, of your over-the-counter (OTC) drug manufacturing facility located in Mequon, WI, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals [Title 21, Code of Federal Regulations, Part 211 (21 CFR 211)]. Your OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include, but are not limited to, the following:

1. Failure to establish scientifically sound and appropriate specifications for raw material and finished product testing.
2. Failure to have a written testing program to assess the stability characteristics of the Swiss Kriss products.
3. Failure to document each significant step in the manufacture, processing, packing or holding of your Swiss Kriss products.
4. Failure to determine theoretical and actual yields, and failure to have the calculations performed by one person and independently verified by a second individual.

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5. Failure to exercise strict control over labeling issued for use in drug product labeling operations.

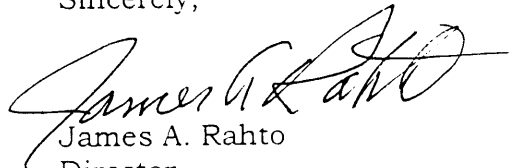
The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that the Food and Drug Administration expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

TPN
CAH/ccl